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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,301	06/02/2005	Chris Vervae	2551-170	1707
23117	7590	06/08/2006	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			SINGH, SATYENDRA K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 10/537,301	Applicant(s) VERVAET ET AL.	
	Examiner Satyendra K. Singh	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 15-17 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>06/02/05; 07/21/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed with the office on May 8th 2006 is duly acknowledged.

Claims 1-7 and 9-14 (groups I and III) have been withdrawn from further consideration.

Claims 8, and 15-17 (group II) are examined on their merits in this office action.

Election/Restrictions

Applicant's election of **group II** (claim 8 and 15-17, a method of promoting wound healing comprising applying the composition of claim 1 to an area of skin in need of said promoting) in the reply filed on May 8th 2006 is acknowledged. Since, applicant's failed to explicitly state in their response whether the election was done with or without traverse, the election has been taken as being made **without traverse**. The inventions of Groups I and III (claims 1-7 and 9-14) are withdrawn from further consideration.

The requirement (for election/restriction as previously set forth by the examiner) is still deemed proper and is therefore made FINAL.

Claims Suggestions

Claim 8 has a minor informality. Claim 8 incorrectly recites (on page 5, line 1 of the specification) "to an area skin" which should be corrected to recite "an area **of** skin". Appropriate correction is requested.

Claim Objections

Claim 8 is objected to because it is an incomplete claim. Claim 8 (directed to a method of promoting wound healing) depends from a non-elected claim 1 for the wound healing composition to be used by the said method. Applicants are requested to

incorporate the limitations of claim 1 into instant claim 8 as a remedial correction or amend the instant claim 8 appropriately.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 recites “the method of claim pharmaceutical composition of claim 8”, which is confusing. It is not clear as to what is being claimed and as to what exactly is applicant’s invention. It is noted that claim 8 (as presented) is drawn to a **method of promoting wound healing** using the composition as claimed in claim 1. In other words, claim 8 is not directed to a pharmaceutical composition but to a method of using such composition (as recited in claim 1). Appropriate clarification and correction is required.

For examination purposes, herein, claim 17, has been treated by the examiner as being dependent from claim 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Bossuyt (US 5,866,167; IDS) in view of Rolf (US 5,804,213; [A]).

Claims are generally directed to a method of promoting wound healing comprising applying the composition of claim 1 (i.e. comprising a non-viable cell lysate and at least one antiflocculant and/or antisedimentation agent such as xanthan gum) to an area of skin in need of said promoting; wherein the wound is at least one of wound and a skin ulcer; wherein said composition is in the form of a dry powder, a suspension, or a solution; wherein said composition is in the form of a gel, a cream, an ointment, or a biocompatible matrix.

Van Bossuyt (IDS) teaches a method of promoting wound healing comprising applying the composition containing a non-viable keratinocyte cell lysate (see Van Bossuyt, abstract, summary of the invention, example 1, column 18-23, and claims 4, 12, and 20, in particular) to an area of skin wound in an swine model animals, in need thereof; wherein the composition is in the form of a dry powder, a suspension, or a solution (see Van Bossuyt, claims 3, 11, and 18, in particular); wherein the composition is in the form of a gel, a cream, an ointment, or a biocompatible matrix (see Van

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Bossuyt, claims 5-8, 13-16, and 21-24, in particular). Van Bossuyt teaches the use of pharmaceutically acceptable vehicles (such as gel, cream, ointment or a biocompatible matrix) to deliver or to apply the said composition onto the skin wounds of the subject in need thereof.

However, a method of promoting wound healing comprising applying a composition containing non-viable cell lysate along with an anti-flocculant and/or anti-sedimentation agent such as **xanthan gum** is not explicitly disclosed by the referenced invention of Van Bossuyt.

Rolf [A] teaches a wound healing composition in the form of a prepackaged dressing including dry particulate solids for forming a pourable, water-based natural or synthetic hydrocolloidal polymeric gel to dress wounds in order to promote wound healing resulting from injury, surgical wounds, or decubitus ulcers (see Rolf, abstract, summary of the invention, columns 7-8, 11-12, and claims, in particular). Rolf teaches the use of xanthan gum as a gelling agent (in order to provide a stable hydrocolloid) for the aqueous composition that can comprise of biologically active components (see Rolf, examples 44-69; column 7, 4th paragraph; and column 8, 2nd paragraph, in particular) in the form of stabilized aqueous/liquid or semi-solid gel matrix that can be freeze-dried in the form of a solid/powder and can be stored for extended period of time.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the composition containing keratinocyte cell lysate used by Van Bossuyt (in the method of promoting skin wound healing in a subject

in need thereof) such that it contains a binding agent such as xanthan gum, as explicitly taught by the referenced invention of Rolf [A].

A person of ordinary skill would have been motivated to use such a hydrocolloid/gelling agent (i.e. xanthan gum) in the composition of Van Bossuyt for use in the method of promoting skin surface wound healing (see the teachings of Van Bossuyt, *supra*) because Rolf provides the benefits (i.e. stabilization of aqueous formulations, suspensions of biologically active agents that can be freeze-dried in solid form, or alternatively, can be used in the gel form) of using such hydrocolloid/gelling agents.

The person of ordinary skill would have had a reasonable expectation of success when modifying the composition of Van Bossuyt containing a keratinocyte cell lysate by adding xanthan gum as a hydrocolloid/gelling agent (to stabilize said composition in order to be used in the method of promoting wound healing of skin in the subject in need thereof) because Rolf provides the method of incorporating such gelling agents in liquid formulations containing biologically active agents such as growth factors, enzymes, proteinaceous molecules, immunostimulators and other pharmaceutical agents (see Rolf, discussion, *supra*). Although the composition taught by Rolf [A] does not explicitly state the anti-flocculant and/or anti-sedimentation properties of the xanthan gum used, such properties are in fact inherently used in the referenced composition to produce stabilized wound healing compositions in the form of a hydrocolloidal gel.

Hence, the benefits accrued from combining the xanthan gum (as taught by Rolf) in the composition of Van Bossuyt (containing biologically active material such as

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aqueous, keratinocyte cell lysate) in order to stabilize said wound healing composition would have been obvious to a person of ordinary skill in the art at the time this invention was made.

As per MPEP 2144.06, "*It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.*" *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

Conclusions

NO claims are allowed.

Pertinent prior art not relied upon in the rejections


1. Fuisz (US 5,622,717; issued on April 22nd 1997), Ulcer prevention method using a melt-spun hydrogel.
2. Obi-Tabot (US 6,046,160; issued on April 4th 2000), Composition and method for enhancing wound healing.
3. Schacht et al (US 6,132,759; issued on Oct 17, 2000), Medicament containing gelatin cross-linked with oxidized polysaccharides.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (alternate Fridays OFF).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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